

Economic Clinical Study Proposal

M2a-Magnum

October 28, 2005

Problem:

We have nothing to justify the M2a-Magnum's high implant cost, specifically data demonstrating that there is economic value to implanting our large metal articulation versus less expensive designs.

What costs would we want to capture?

1. Surgeon & staff time
2. Operating room time
3. Total cost of hospital stay
4. Rehabilitation length and costs
5. Drugs
6. Complications/Re-admissions/Revisions
7. Lost work time

How do we capture these costs?

I don't know. Can we partner with a hospital and send in an auditor to work with administration to capture costs? Are there hospitals that we have an exceptionally good relationship that would be open to working with us on this?

Will the data we capture be applicable to our audience?

Assuming we have more than 1 option for selecting an institution, it should be a high volume hospital, not a surgery center.

Do we do just a case study? I think that if we determine we cannot or should not do a more encompassing study, we should absolutely do perhaps several case studies.

How long do we run the study to capture "enough" dislocation data?

Most dislocations happen quite early, within the first few months. I think 3 months would be an adequate time frame. This was Dr. Cuckler's time frame on his study of the M2a-38.

Do we want to consider revisions as well?

If a revision is directly attributable to dislocation or device-specific failure, yes.

If we find one is better than the other, are we shooting ourselves in the foot?

Our hope is to find that the M2a-Magnum is superior. Here is an ideal finding:

"In our four month study of 50 patients with the M2a-Magnum™ Metal-on-Metal Hip, we found a clinically significant reduction in dislocations, a faster reclamation of joint function, and improved Harris Hip Scores at all time intervals versus the control group of smaller diameter metal-on-polyethylene hips."

Derek Edgar

Exhibit 11

VF 12-12-18

PRODBEG	BMT-MM00337373
PRODEND	BMT-MM00337373
PRODBEGATTACH	BMT-MM00337373
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PAGECOUNT	1
CUSTODIAN	Design
AUTHOR	dedgar
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